

PE



ATTORNEY DOCKET No.:2006078-0009 (JG/12987.54)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: BOILEAU, *et al.*  
 Serial No.: 10/549,796  
 Filed: September 19, 2005  
 Corresp. to: PCT/CA2004/000453  
 Int. Filing Date: March 25, 2004  
 Earliest Priority: March 25, 2003  
 Title:: PHEX SUBSTRATES AND METHODS USING SAME

Examiner: NYA  
 Group Art Unit: NYA

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

Certificate of Mailing	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
January 17, 2006	<i>Kathy Hart Gagnon</i>
Date	Signature
	<i>KATHY HART GAGNON</i>
	Typed or Printed Name of person signing

**TRANSMITTAL LETTER**

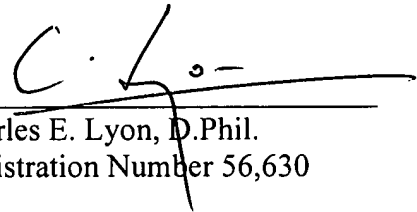
Enclosed for filing in the above-referenced patent application please find the following documents:

1. Statement Filed Pursuant to the Duty of Disclosure Under 37 CFR §§1.56, 1.97 and 1.98 (6 pages);
2. Form PTO-1449 (5 pages);
3. Cited Art (39 References); and
4. Return-Receipt Postcard.

Please charge any fees that may be required or credit any overpayments to our Deposit Account No. 03-1721.

Respectfully submitted,  
CHOATE, HALL & STEWART LLP

Dated: January 17, 2006



Charles E. Lyon, D.Phil.  
Registration Number 56,630

PATENT DEPARTMENT  
CHOATE, HALL & STEWART LLP  
Two International Place  
Boston, Massachusetts 02110  
Tel: (617) 248-5000  
Fax: (617) 248-4000



ATTORNEY DOCKET No.:2006078-0009 (JG/12987.54)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	BOILEAU, <i>et al.</i>	Examiner:	NYA
Serial No.:	10/549,796	Group Art Unit:	NYA
Filed:	September 19, 2005		
Corresp. to:	PCT/CA2004/000453		
Int. Filing Date:	March 25, 2004		
Earliest Priority:	March 25, 2003		
Title::	PHEX SUBSTRATES AND METHODS USING SAME		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450/Alexandria, VA 22313-1450

January 17, 2006  
Date

*Kathy Hart Gagnon*  
Signature

KATHY HART GAGNON  
Typed or Printed Name of person signing

**STATEMENT FILED PURSUANT TO THE  
DUTY OF DISCLOSURE UNDER 37 CFR §§ 1.56, 1.97 AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants request consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or
- ☐ A *supplemental* Information Disclosure Statement.

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

☒ A copy of each cited reference not indicated with a \* is included, except for those for which the requirement is waived pursuant to USPTO OG Notice of 8/5/03;

☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ Does not contain non-English language citations;
- ☐ Does contain non-English language citations, of which the following is a concise explanation:
  - ☐ Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

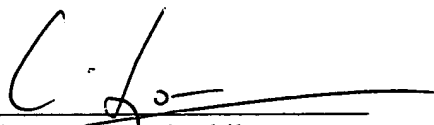
1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and

3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

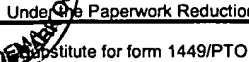
Respectfully submitted,  
CHOATE, HALL & STEWART LLP

Dated: January 17, 2006

  
\_\_\_\_\_  
Charles E. Lyon, D.Phil.  
Registration Number 56,630

PATENT DEPARTMENT  
CHOATE, HALL & STEWART LLP  
Two International Place  
Boston, Massachusetts 02110  
Tel: (617) 248-5000  
Fax: (617) 248-4000





PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

Sheet	1	of	5
-------	---	----	---

**Complete if Known**

Application Number	10/549,796
Filing Date	September 19, 2005
First Named Inventor	Boileau et al.
Art Unit	
Examiner Name	
Attorney Docket Number	2006078-0009

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	B1	WO 00/50580	08-31-2000	CRINE, Philippe et al.		
	B2	WO 02/15918	02-28-2002	BOILEAU, Guy		

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Office. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.*

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)	<b>Application Number</b>		10/549,796		
	<b>Filing Date</b>		September 19, 2005		
	<b>First Named Inventor</b>		Boileau et al.		
	<b>Art Unit</b>				
	<b>Examiner Name</b>				
<b>Sheet</b>	2	<b>of</b>	5	<b>Attorney Docket Number</b>	2006078-0009

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	ARAUJO, M.C. et al., Biochemistry, 2000, Vol. 39, pp 8519-8525.	
	C2	BACKES, B.J. et al., Nature Biotechnology, 2000, Vol. 18, pp 187-193.	
	C3	BECK, L. et al., J. Clin. Invest., 1997, Vol. 99, No. 6, pp 1200-1209.	
	C4	BLYDT-HANSEN, T.D. et al., Pediatr. Nephrol., 1999, Vol. 13, pp 607-611.	
	C5	BOILEAU, G. et al., Biochem J., 2001, Vol. 355, pp 707-713.	
	C6	BONVOULOIR, N. et al., DNA and Cell Biology, 2001, Vol. 20, No. 8, pp 493-498.	
	C7	CRINE, P. et al., Cell-Surface Peptidases in Health and Disease, 1997, pp 79-98.	
	C8	DE BEUR, S.M.J. et al., J. of Bone and Mineral Research, 2002, Vol. 17, No. 6, pp 1102-1110.	
	C9	ECONS, M.J. et al., The New England J. of Medicine, 1994, Vol. 330, No. 23, pp 1679-1681.	
	C10	FOSSIEZ, F. et al., Biochem. J., 1992, Vol. 284, pp 53-59.	

<b>Examiner Signature</b>		<b>Date Considered</b>	
---------------------------	--	------------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Sheet 3 of 5	Application Number	10/549,796
	Filing Date	September 19, 2005
	First Named Inventor	Boileau et al.
	Art Unit	
	Examiner Name	
	Attorney Docket Number	2006078-0009

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C11	FRANCIS, F. et al., Nature Genetics, 1995, Vol. 11, pp 130-136.	
	C12	GHADDAR, G. et al., Biochem J., 2000, Vol. 347, pp 419-429.	
	C13	GRIEFF, M. et al., Biochemical and Biophysical Research Communications, 1997, Vol. 231, pp 635-639.	
	C14	GUO, R. et al., Am. J. Physiol. Endocrinol. Metab., 2001, Vol. 281, pp E837-E847.	
	C15	HARRIS, J.L. et al., PNAS, 2000, Vol. 97, no. 14, pp 7754-7759.	
	C16	HERMAN, L.W. et al., Molecular Diversity, 1996, Vol. 2, pp 147-155.	
	C17	HIRATA, I.Y. et al., Letters in Peptide Science, 1994, Vol. 1, pp 299-308.	
	C18	LAEMMLI, U.K., Nature, 1970, Vol. 227, pp 680-685.	
	C19	LAJEUNESSE, D. et al., Kidney International, 1996, Vol. 50, pp 1531-1538.	
	C20	LIPMAN, M.L. et al., The J. of Biochemical Chemistry, 1998, Vol. 273, No. 22, pp 13729-13737.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/549,796
		Filing Date	September 19, 2005
		First Named Inventor	Boileau et al.
		Art Unit	
		Examiner Name	
Sheet 4	of 5	Attorney Docket Number	2006078-0009

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C21	MARSH, W.L., Transfusion, 1992, Vol. 32, No. 2, pp 98-101.	
	C22	MELDAL, M., Methods: A Companion to Methods in Enzymology, 1994, Vol. 6, pp 417-424.	
	C23	ROQUES, B.P. et al., Pharmacological Reviews, 1993, Vol. 45, No. 1, pp 87-146.	
	C24	ROWE, P.S.N. et al., Genomics, 2000, Vol. 67, pp 54-68.	
	C25	RUCHON, A.F. et al., The J. of Histochemistry & Cytochemistry, 1998, Vol. 46, No. 4, pp 459-468.	
	C26	RUCHON, A.F. et al., J. of Bone and Mineral Research, 2000, Vol. 15, No. 8, pp 1440-1450.	
	C27	SCHECHTER, I. et al., Biochemical and Biophysical Research Communications, 1968, Vol. 32, No. 5, pp 898-902.	
	C28	SCHIAVI, S.C. et al., Current Opinion Nephrol. Hypertens., 2002, Vol. 11, pp 423-430.	
	C29	SHIMADA, T. et al., PNAS, 2001, Vol. 98, No. 11, pp 6500-6505.	
	C30	SHIROTANI, K. et al., The J. of Biological Chemistry, 2001, Vol. 276, No. 24, pp 21895-21901.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/549,796
		Filing Date	September 19, 2005
		First Named Inventor	Boileau et al.
		Art Unit	
		Examiner Name	
Sheet 5	of 5	Attorney Docket Number	2006078-0009

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C31	SONG, E-S. et al., The J. of Biological Chemistry, 2001, Vol. 276, No. 2, pp 1152-1155.	
	C32	TENENHOUSE, H.S., Nephrol. Dial. Transplant., 1999, Vol. 14, pp 333-341.	
	C33	TENENHOUSE, H.S. et al., The Metabolic and Molecular Bases of Inherited Diseases, 2001, Chapter 197, pp 5039-50678.	
	C34	TRAPANI, A.J. et al., J. of Cardiovascular Pharmacology, 1995, Vol. 26, Suppl. 3, pp S69-S71.	
	C35	TURNER, A.J. et al., The FASEB J., 1997, Vol. 11, pp 355-364.	
	C36	VALDENNAIRE, O. et al., Biochem J., 2000, Vol. 346, pp 611-616.	
	C37	WHITE, K.E. et al., Nature Genetics, 2000, Vol. 26, pp 345-348.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.